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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Peter James Watts

Serial No.: 09/269,903

Art Unit: 1615

Filed: May 6, 1999

Examiner: Not Yet Assigned

For: *COLONIC DELIVERY OF WEAK ACID DRUGS*

Assistant Commissioner for Patents
Washington, D.C. 20231

#7
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12/1/99

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicant submits an Information Disclosure Statement, including four (4) pages of Form PTO-1449 and a copy of each document cited therein.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It therefore is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 01-2507. A duplicate of this transmittal is enclosed to facilitate the process.

U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
4,663,308	05-05-1987	Saffran, et al.	514/3
4,871,549	10-03-1989	Ueda, et al.	424/494
4,945,080	07-31-1990	Lindstrom, et al.	514/29
4,963,573	10-16-1990	Freyne, et al.	514/357
5,310,558	05-10-1994	Pozzi, et al.	424/476
5,514,663	05-07-1996	Mandel	514/33
5,631,022	05-20-1997	Mandel, et al.	424/456
5,651,983	07-29-1997	Kelm, et al.	424/452
5,656,290	08-12-1997	Kelm, et al.	424/456

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5,686,106 11/11/1997 Kelm, et al. 424/463

Foreign Patent Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
42 36 025 A1	04-28-1994	Merck Patent GmbH	DE
2 166 051 A	04-30-1986	Alza Corp.	GB
2 174 599 A	11-12-1986	Norwich Eaton Pharmaceuticals Inc.	GB
2 238 243 A	05-29-1991	National Research Development Corp.	GB
0 221 601 A1	05-13-1987	Janssen Pharmaceutica N.V.	EP
0 338 383 A2	04-11-1989	Schwarz Pharma AG	EP
0 365 947 A1	05-02-1990	Pharmacia AB	EP
0 513 035 B1	10-20-1993	Danbiosyst UK Ltd.	EP
0 519 870 A1	12-23-1992	Spirig AG Pharmazeutische Präparate	EP
0 572 942 A2	12-08-1993	Poli Industria Chimica S.p.A.	EP
0 621 032 A1	10-26-1994	Ciba-Geigy AG	EP
0 640 337 A2	03-01-1995	SS Pharmaceutical Co. Ltd.	EP
0 673 645 A2	09-27-1995	F. Hoffmann-La Roche AG	EP
WO 89/11269 A1	11-30-1989	Agricultural and Food Research Council	PCT
WO 90/13286 A1	11-15-1990	Chugai Seiyaku Kabushiki Kaisha	PCT
WO 91/16881 A1	11-14-1991	Yissum Research Development Company of the Hebrew University of Jerusalem	PCT
WO 92/01457 A1	02-06-1992	Rhodes, et al.	PCT
WO 92/14452 A1	09-03-1992	Rhodes, et al.	PCT
WO 95/06464 A1	03-09-1995	Galenik Labor Freiburg GMBH	PCT
WO 95/14037 A1	05-26-1995	Ibah, Inc.	PCT
WO 95/35100 A1	12-28-1995	Danbiosyst UK Ltd.	PCT
WO 96/30016 A2	10-03-1996	Janssen Pharmaceutica N.V.	PCT

Publications

ASHFORD, et al., "In Vivo Assessment of Colonic Drug Delivery Systems," *Br. Pharm. Conference Abstract* 13, p. 1049 (1992).

BURNS, et al., "An in vitro assessment of liquid-filled Capill ® potato starch capsules with biphasic release characteristics," *Int. J. Pharm.* 134:223-30 (1996).

HEALEY, "Enteric Coatings and Delayed Release" in Drug Delivery to the Gastrointestinal Tract (Hardy, et al., eds.) Ellis Horwood:Chichester, 1989.

KENYON, et al., "The effect of food on the in vivo behaviour of enteric coated starch capsules," *Int. J. Pharm.* 112:207-13 (1994).

KOPE EK, et al., "Polymers for colon-specific drug delivery," *J. Control. Rel.* 19:121-30 (1992).

MILOJEVIC, et al., "In Vitro and In Vivo evaluation of amylose coated pellets for colon specific drug delivery," *Proceed. Intern. Symp. Control. Rel. Bioact. Mater.* 20:288-89 (1993).

RUBINSTEIN & GLIKO-KABIR "Synthesis and swelling-dependent enzymatic degradation of borax-modified guar gum for colonic delivery purposes," *S.T.P. Pharma Sciences* 5:41-46 (1995).

RUBINSTEIN, et al., "Colonic Drug Delivery: Enhanced Release of Indomethacin from Cross-Linked Chondroitin Matrix in Rat Cecal Content," *Pharm. Res.* 9(2):276-78 (1992).

RUBINSTEIN, et al., "In Vitro Evaluation of Calcium Pectinate: A Potential Colon-Specific Drug Delivery Carrier," *Pharm. Res.* 10(2):258-63 (1993).

SIEFKE, et al., "Colon Targeting with β -CD Matrix Films," *Eur. J. Pharm. Biopharm.* 40 (suppl.):33S (1994).

THE UNITED STATES PHARMACOPOEIA, USP23, pp. 1791-93 (1994).

VAN DEN MOOTER, "Azo polymers for colon-specific drug delivery," *Int. J. Pharm.* 87:37-46 (1992).

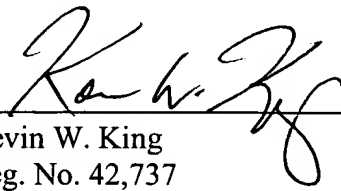
WILDING, et al., "Gastrointestinal Transit and Systemic Absorption of Captopril from a Pulsed-Release Formulation," *Pharm. Res.* 9(5):654-57 (1992).

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Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicant invites the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicant is of the opinion that his claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,


Kevin W. King
Reg. No. 42,737

Dated: November 18, 1999

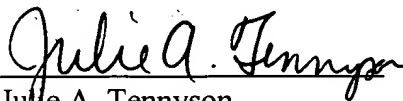
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Certificate of Mailing under 37 C.F.R. § 1.8(a)

I hereby certify that this Information Disclosure Statement, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: November 18, 1999


Julie A. Tennyson